No. 03-1237

Supreme Court, U.S.
FILED
MAR 2 2 2005
OFFICE OF THE CLERK

In The
Supreme Court of the United States

MERCK KGAA,

Petitioner,

v.

INTEGRA LIFESCIENCES I, LTD. and
THE BURNHAM INSTITUTE and
TELIOS PHARMACEUTICALS, INC.

**On Writ Of Certiorari To The
United States Court Of Appeals
For The Federal Circuit**

BRIEF OF AMICI CURIAE APPLERA CORPORATION AND ISIS PHARMACEUTICALS, INC. IN SUPPORT OF RESPONDENTS

EDWARD R. REINES
Counsel of Record

PAUL T. EHRLICH
WEIL, GOTSHAL & MANGES LLP
201 Redwood Shores Parkway
Fifth Floor
Redwood Shores, CA 94065
(650) 802-3000

*Counsel for Amici Curiae
Applera Corporation
Isis Pharmaceuticals, Inc.*

COCKLE LAW BRIEF PRINTING CO. (800) 225-6964
OR CALL COLLECT (402) 342-2831

TABLE OF CONTENTS

		Page
I.	STATEMENT OF INTEREST	1
II.	INTRODUCTION	3
III.	PETITIONER'S REQUEST FOR A BROAD "DRUG RESEARCH AND DEVELOPMENT" EXEMPTION IGNORES THE PLAIN MEANING OF THE STATUTE	7
	A. The Statutory Term "Solely" Must Be Given Real Meaning	7
	B. The Attempts By Petitioner And Its Allies To Address The Meaning Of "Solely" Treat That Term As Surplusage	11
	C. Petitioner And Its Allies Misinterpret The Word "Uses," As Used In Section 271(e)(1), By Conflating It Improperly With "Act Of Infringement"	13
IV.	RESPECTING THE WORDS OF SECTION 271(e)(1) RIGHT-SIZES THE EXEMPTION AND ALIGNS IT WITH ITS ORIGINAL PURPOSE	16
V.	THE EXEMPTION SOUGHT BY PETITIONER WILL SET BACK, NOT ADVANCE, PUBLIC HEALTH	19
VI.	CONCLUSION	23

TABLE OF AUTHORITIES

Page

CASES

Duncan v. Walker, 533 U.S. 167 (2001) 7

Eli Lilly & Co. v. Medtronic, Inc., 496 U.S. 661 (1990) 18

Integra Life Sciences 1, Ltd. v. Merck KG, 331 F.2d 860 (Fed. Cir. 2003) 18

Neumann v. AT&T Communications, Inc., 376 F.3d 773 (8th Cir. 2004) 9

Nixon v. United States, 506 U.S. 224 (1993) 7, 8

Scripps Clinic & Research Foundation v. Genentech, Inc., 666 F. Supp. 1379 (N.D. Cal. 1987) 10, 16

Shaw v. Delta Air Lines, Inc., 463 U.S. 85 (1983) 7

United States v. Clingan, 254 F.3d 624 (6th Cir. 2001) 8

United States v. Minnesota, 97 F. Supp. 2d 973 (D. Minn. 2000) 8

White v. Kentuckiana Livestock Market, Inc., 397 F.3d 420 (6th Cir. 2005) 9

FEDERAL STATUTES

35 U.S.C. § 156 2

35 U.S.C. § 271(a) 13, 14

35 U.S.C. § 271(e) 3

35 U.S.C. § 271(e)(1) ..... *passim*

TABLE OF AUTHORITIES – Continued

Page

OTHER AUTHORITIES

H.R. Rep. No. 857, *reprinted in* 1984 U.S.C.A.N.N. 2684 18

Kevin E. Noonan, *Paradise Lost: The Uncertain Future Of Research Tool Patents*, 15 No.3 J. Proprietary Rts. 1, 8 21

Tufts Center for the Study of Drug Development, *Backgrounder: How New Drugs Move Through The Development and Approval Process* (November 1, 2001) *at* http://csdd.tufts.edu/NewsEvents/RecentNews.asp?newsid=4 15

I.

STATEMENT OF INTEREST[1]

This brief is submitted by Applera Corporation (including Applied Biosystems and Celera Genomics), and Isis Pharmaceuticals (referred to collectively as "Amici").

Amici are companies whose technological contributions epitomize the innovation that the Constitutional mandate for a patent system is intended to promote. Amici's array of inventions are primarily "platform technologies" in the biotech and pharmaceutical area, the proverbial "shoulders of giants" on which other innovators stand. Indeed, Amici's efforts have led to fundamental enabling technologies such as the polymerase chain reaction ("PCR"), and groundbreaking drug discovery tools such as antisense technology. Amici depend on a vibrant patent system that allows them to fund future innovation by licensing these enabling technologies to others.

Applera Corporation is a world-renowned innovator whose inventions routinely establish benchmarks in the global economy and provide springboards for innovation. Through its Applied Biosystems division, Applera has developed and commercialized fundamental instruments and tools that form the foundation for the modern biotech and pharmaceutical industries. These include instruments and basic techniques for automatically synthesizing DNA with any genetic code desired, finding and replicating

---

[1] Pursuant to Rule 37.6, none of the parties or their counsel has contributed substantively or monetarily to the preparation of this brief. Specifically, only Amici and their counsel have contributed to the preparation or submission of this brief. The consents of the parties are being lodged herewith.

DNA, and sequencing DNA and proteins. Through its Celera Genomics division, Applera has created tools for gene discovery and sequencing that have accelerated the comprehension of the human genome by decades. Applera's technologies are core to the biotech and pharmaceutical industries and are disseminated through a robust program of licensing that allows all researchers to be lifted by this rising tide of innovation.

Isis Pharmaceuticals is a leading drug discovery and development company focused exclusively on the therapeutic target, RNA. Isis is a pioneer in the field of antisense technology, which aims to control protein expression by intervening at the RNA level. Antisense technology is one component in a suite of valuable tools that Isis has created to facilitate drug discovery at every stage of the process. Other Isis inventions include technologies for rapid validation of targets, medicinal chemistries and formulations useful in basic research and for optimizing delivery of drug candidates, and improved manufacturing and analytical tests and standards for evaluating therapeutic agents. Isis holds more than 1400 patents worldwide and depends on its ability to license its patent portfolio for its continued success.

Amici generate the tools that constitute the lifeblood of the pharmaceutical industry. Amici's tools are diverse and run the gamut from bench instruments to medicinal chemistries. All of these inventions enable the drug discovery process to proceed while remaining ancillary to the ultimate drug products. Thus, unlike many of the other amici from the pharmaceutical industry, Applera and Isis do not often reap the benefit of the patent term extension granted to certain therapeutics by 35 U.S.C. § 156. However, Amici's businesses are threatened by overaggressive

attempts to expand the exemption of 35 U.S.C. § 271(e) in ways that would destroy the value in foundational tool patents. While others espouse unduly one-sided views of the cost of patent law, Amici have witnessed first hand the profound growth that can be achieved when the intellectual property of the entire industry is protected, consistent with the patent laws and the will of Congress.

In sum, Amici are well-positioned to address the balanced trade-off inherent in the patent system that tolerates short term costs of patent licenses to achieve the long term benefits that accrue in a system that rewards all innovation. Amici eschew the short-sighted attempts to shift the costs of invention almost entirely from one set of innovators to another.

II.

INTRODUCTION

Petitioner and its allies ignore the critical word "solely," which sits squarely in the middle of Section 271(e)(1). Indeed, the United States does not address this statutory language until page 20 of its brief – and then the subject is reduced to a footnote. As one would expect, the statutory term "solely" should be given meaning because it is not mere hollow text needlessly cluttering the statute.

The plain text of the statute should not be ignored. Specifically, Section 271(e)(1) provides that the FDA exemption applies "*solely for uses* reasonably related to the development and submission of information under a Federal Law." Whether viewed from the perspective of a lay person, or a legal scholar trained in statutory construction, these words unmistakably mean that the exemption

applies to infringing activities undertaken *solely* for purposes of regulatory approvals. This is particularly true because the structure of the statute shows that the word "uses" in the phrase "solely for uses" refers to the *purposes* of the infringing act (e.g., clinical testing, marketing), not to the infringing act itself. Thus, "solely for uses" necessarily means "solely for *purposes*" reasonably related to the development and submission of information under a federal drug law.

As the statute states in straightforward terms, to qualify for the exemption, the purpose of any infringement must be solely for regulatory reasons – a subjective inquiry. That an infringement could theoretically result in information of a kind that someone might submit to the FDA is insufficient to gain immunity if the information was never even supposed to be used for regulatory purposes at all. Even if it were intended solely to obtain regulatory approvals, such an intent must also be reasonable because the statute provides that the purpose must be "reasonably related" to the regulatory approval process – an objective inquiry. That an infringer commits acts of infringement for the purpose of FDA approval is insufficient to gain immunity if the information generated is not reasonably related to the approval process. Thus, the language and logic of the statute dictate that the exemption has both a subjective *and* objective requirement. The fatal error in Petitioner's position is that it ignores the statutory term "solely for uses" and consequently ignores the subjective requirement of the statute. Indeed, neither Petitioners, nor its allies, explain what real meaning "solely" would have under their reading of the statute.

For ease, Amici have collected in one table the sum total of the arguments to date submitted to this Court

from those who made any effort to take on the textual significance of the word "solely." The table is attached as the appendix to this brief. The few attempts to explain away the use of "solely" in the statute are unsatisfying, at best.

Giving "solely" its natural meaning is supported by the legislative history. The legislative history makes clear that the exemption was designed to address improper patent term extensions, not to repeal the patent law broadly in the area of drug and medical device research and development. Section 271(e)(1) was merely intended to avoid the situation where the regulatory approval process resulted in an undeserved *de facto* extension of a patent's life. It thus makes sense that only activities used for regulatory approvals are exempt under the statute. Although the terms of the statute are not limited to immunizing infringement in the generic drug approval process, the exemption fits that circumstance like a glove. Because a generic drug is a copy of an existing product, there is no drug discovery necessary. What is necessary is to have a generic drug approved by the FDA by the time the patent on the proprietary version of the drug expires. This simply requires immunity from infringement for the development and submission of information to the FDA for regulatory approval to establish the generic copy is what it is supposed to be.

The presence of the phrase "solely for uses" is not a mistake or surplusage because it ensures that the exemption remains balanced as Congress intended. This is not a case where clear statutory language appears to be the unfortunate result of a stumble by the drafter. If that were so, a tough statutory construction question might exist. But it is not so. Respecting the phrase "solely for uses"

right-sizes the exemption and honors the sensible policy balance struck by Congress and blessed by the President. A statute that authorizes the uncompensated infringement of a whole class of patents was not undertaken lightly – or without balance. Yet, petitioner and its allies mistreat the exemption as though it were a sweeping suspension of the patent law for the drug discovery and development process generally. To interpret the statute in this way would be manifestly unfair to those who innovate and invest in the technology protected by such patents.

The potential cost of ignoring the term "solely" is staggering. The engine for modern drug discovery is the biotech industry. The biotech industry has provided an increasingly rich set of tools that are used for basic research, drug discovery, and drug development. Yet, if Section 271(e) is construed as the drug companies would like, the patents on such tools could be infringed cost-free. The patents protecting those innovations would lose their value and the incentive to create new tools would diminish dramatically. This is particularly true because the patent rights preventing copying are frequently the main source of value for the large investments made by tool creators.

In sum, limiting the exemption to immunity for infringement "solely for" efforts to obtain regulatory approval avoids major policy problems, properly gives effect to all terms of the statute, and respects the balance memorialized in the plain terms of the statute.

III.

PETITIONER'S REQUEST FOR A BROAD "DRUG RESEARCH AND DEVELOPMENT" EXEMPTION IGNORES THE PLAIN MEANING OF THE STATUTE

A. The Statutory Term "Solely" Must Be Given Real Meaning

As this Court has explained repeatedly, "it is a cardinal principle of statutory construction" that the Court has a "duty 'to give effect, if possible, to every clause and word of a statute.'" *Duncan v. Walker*, 533 U.S. 167, 174 (2001). Further, the Court is "reluctant to treat statutory terms as surplusage in any setting" *Id.* (citations omitted). The Court is "especially unwilling" to treat a term as surplusage when it occupies a pivotal place in the statute. *Id.*

Here, the phrase "solely for uses" occupies a central place in Section 271(e) and cannot be ignored. Not surprisingly, this Court has recognized that "solely" has an established meaning that should be given effect. In *Shaw v. Delta Air Lines, Inc.*, 463 U.S. 85, 106-07 (1983), this Court gave meaning to the word "solely" to find that an employee benefit plan is exempt from federal ERISA preemption *only* insofar as its terms are "solely" for the purpose of complying with state disability law and include nothing more.

In *Nixon v. United States*, 506 U.S. 224, 230-31 (1993), the issue was whether the Constitutional phrase "the Senate shall have the *sole* Power to try all impeachments" meant that the Senate was the only entity that had the authority to determine the impeachment issue. The Court criticized the petitioner for failing to meaningfully address

the word "sole," which this Court termed of "considerable significance." *Id.* The Court then set forth the standard dictionary meaning of "sole" that it applied:

> "Sole" is defined as "having no companion," "solitary," "being the only one," and "functioning . . . independently and without assistance or interference."

Id. (*quoting* Webster's Third New International Dictionary 2168 (1971)). Based on this conclusion, this Court ruled that the Senate had the sole (only) Power to resolve the impeachment issues.[2] *Id.*

Courts have frequently acknowledged that "solely" has a clear meaning that must be applied – even where it makes a legal test tough to meet. In *United States v. Clingan*, 254 F.3d 624, 626 (6th Cir. 2001), the court gave meaning to the word "solely" in the criminal context finding that the criminal's use of firearms for self-defense purposes meant that those firearms were not used "*solely* for lawful sporting or collection purposes" and thus greater punishment was appropriate. The court explained that the plain meaning of "solely" mandated that outcome: "'Solely' means SINGLY, ALONE . . . to the exclusion of alternative or competing things." (ellipses in original) (citations

[2] In a particularly clear statement, one judge explained that "solely" is a legally significant word with an established meaning that should not be ignored when present in a statute:

> The presence of the word "solely" was not an idle choice; it has a distinct legal meaning. "Solely" means "exclusively," and directs the Court to look to only the single factor identified.

United States v. Minnesota, 97 F. Supp. 2d 973, 984 (D. Minn. 2000) (citations omitted).

omitted) (*quoting* Webster's Third New International Dictionary 2168 (1986)); *see also Neumann v. AT&T Communications, Inc.*, 376 F.3d 773, 783 (8th Cir. 2004) ("'Solely' means 'to the exclusion of alternate or competing things.'").

In *White v. Kentuckiana Livestock Market, Inc.*, 397 F.3d 420, 425-26 (6th Cir. 2005), the Court ruled that "solely because" in the context of bankruptcy discrimination means that the challenged employment decision must have been based *only* on the employee's bankruptcy for a claim to exist. In giving the word "solely" its standard meaning, the court acknowledged that "the decision of Congress to include the phrase 'solely because' in § 525(b) makes it harder for a plaintiff to prove bankruptcy discrimination than to prove discrimination on the basis of race, or sex, or age" but concluded that the use of the word "solely" reflected Congress's intent to do exactly that.

In the context of Section 271(e)(1), "solely" must mean that, to fall within the exemption, the *only* purpose that can be made of an otherwise infringing act is "solely for uses reasonably related to the development and submission of information under a Federal Law." If the exemption were to be construed to apply to so-called "dual uses," the word "solely" would be erased improperly from the statute. "Dual uses" occur, for example, when an infringing act is used not only for FDA regulatory approval, but also for commercial purposes such as identifying the best drug candidates from a large family of potential drugs or selling a product to thousands of customers who might use them in clinical trials. Stated most simply, the concept of "sole" does not encompass the concept of "dual."

The clearest way of demonstrating that "solely" is not surplusage is to consider the statute with that limitation removed. The modified Section 271(e)(1) would read in relevant part: "[acts of infringement are exempt] for uses reasonably related to [FDA regulatory approval]." Saying that acts are exempt if used for purposes reasonably related to FDA regulatory approval necessarily insulates "dual uses" from infringement – if at least one use is reasonably related, the act is not an infringement. For "solely" to have meaning, it must mean that the exemption is forfeited where an act of infringement is not used "*solely* for uses reasonably related" but is used for non-regulatory uses as well.

In *Scripps Clinic & Research Foundation v. Genentech, Inc.*, 666 F. Supp. 1379, 1396 (N.D. Cal. 1987), Judge Schwarzer got it right when he concluded that the term "solely" in Section 271(e)(1) precludes "dual use" infringements from the exemption:

> The construction of § 271(e)(1) that Genentech urges the Court to adopt would, in effect, **eliminate the express statutory limitation "solely for"** and thereby immunize any use of a patented invention so long as some aspect of that use is reasonably related to FDA testing. This broad construction defies the plain mandate of the statute and the intent of Congress. The statute's meaning is clear: the use of a patented invention is protected so long as that use is solely for purposes reasonably related to meeting the reporting requirements of federal drug laws.

(emphasis supplied).

B. The Attempts By Petitioner And Its Allies To Address The Meaning Of "Solely" Treat That Term As Surplusage

Petitioner and some of its allies have attempted to respond to the Federal Circuit's reliance on the word "solely" in the statute. However, these attempts are unsatisfying, at best. Petitioner expends only three conclusory sentences on this subject. Petitioner's Brief at 29. The gist of Petitioner's argument is that solely "means only that a drug innovator's freedom to use a patented invention under the FDA exemption is not a license to infringe in other ways, such as commercial exploitation." *Id.* If this were correct, "solely" would merely represent the truism that infringement outside of the exemption is not protected by the exemption. This treatment of "solely" would necessarily render it surplusage in violation of this Court's precedents identified above.

In a different part of its brief, Petitioner makes perfectly clear that it is giving no meaning to the word "solely." Petitioner broadly argues that any experiment that could yield information theoretically relevant to the FDA is protected without regard to whether the purpose of the infringement is for the regulatory approval process at all:

> Congress insulated *any* experiment that would yield the 'information' from any experiment, so long as it would be reasonable for the researcher to believe the experiment could generate information of a sort the FDA considers at some point in its role as a regulator of drugs.

Id. at 28-29 (emphasis in original). Petitioner's argument expressly would include as exempt an experiment merely if it "could generate information of a sort the FDA considers at some point" even if that is not the purpose of the

infringement at all. Petitioner's argument would also include as exempt the *identification* of drug candidates in the first instance from among thousands of compounds. Petitioner's Brief at 6 ("even tens of thousands"). Yet, this too involves commercial purposes well beyond mere regulatory approvals.

The United States' brief also reads the term "solely" right out of the statute. In its 30-page brief, the United States' argument on this key statutory language is reduced to a footnote. In that footnote, the brief struggles unsuccessfully to justify how the exemption could immunize infringements pursued for commercial purposes, such as marketing and product development, notwithstanding the presence of the word "solely":

> The statute authorizes making, using, selling, or offering to sell a patented invention "solely for uses reasonably related to the development and submission of information" to FDA. 35 U.S.C. 271(e)(1). Because "solely" modifies "uses," it makes clear that a researcher is not protected by the exemption insofar as he or she engages in uses that are not, in their entirety, reasonably related to the development and submission of information to FDA. "Solely" does not, however, modify "reasonably related." Thus, as long as the full extent of a particular use is reasonably related to the development and submission of information, that use is protected even if it also advances other objectives, such as product development or marketing. See *Amgen, Inc. v. Hoechst Marion Roussel, Inc.*, 3 F. Supp. 2d 104, 107-108 (D. Mass. 1998). But the exemption is inapplicable to the extent that a portion of the particular use at issue does not satisfy the reasonable relationship test.

United States' Brief at 20 n. 5. Because "solely" modifies "use," if the infringing acts are used, for example, for marketing (marketing obviously is not required for FDA approval), it is simply illogical for the United States to argue that such a "use" is *solely* for regulatory approval and thus within the statutory scope of the exemption. That the United States could not identify in clear terms a meaning for "solely" under its reading of the statute, illustrates vividly that a broad exemption of the kind now desired by the government is incompatible with the statutory language selected by Congress.[3]

C. Petitioner And Its Allies Misinterpret The Word "Uses," As Used In Section 271(e)(1), By Conflating It Improperly With "Act Of Infringement"

It is important to appreciate that the second instance of "uses" in the statute – which is in the phrase "solely for uses" – is not referring to "use" as an act of infringement under Section 271(a), but rather refers to the *purpose* of the otherwise infringing acts.

There are three reasons why this must be true. First, the statute would have used the phrase "acts of infringement" instead of "uses" if that had been the intent. After all, the phrase "act of infringement" was used earlier in the statute when that was what was intended. Second, "acts of infringement" and "uses" mean two very different things and cannot be treated as interchangeable. Section 271(a), the basic direct infringement statute, defines an

---

[3] Attached as the Appendix is a table collecting the "solely" arguments by all those who have already submitted a brief.

act of infringement as including the following types of acts: making, using, offering to sell, selling or importing. Indeed, this same list of acts of infringement is recited in Section 271(e)(1). "Use" is only one sub-class of acts of infringement as defined in both Section 271(a) and Section 271(e). Thus, if solely for "uses" in Section 271(e) were to refer to "use" as an act of infringement, instead of "use" as a purpose, it would exclude from the exemption whole classes of acts (selling, making, importing, and offering to sell) that are undisputedly within the exemption. That makes no sense. Third, the phrase "solely for" immediately before "uses" connotes purpose and thus confirms that the overall phrase "solely for uses" refers to the intended purpose of the act and is not merely a reference to an act itself.

Petitioner's and the United States' arguments muddy the waters around "solely" by conflating "act of infringement" and "use" to shift the inquiry to whether a particular infringing act can be reasonably related to the regulatory approval process. This is not the proper question. Because infringing acts have multiple potential purposes, the question is whether the particular *purpose* of the infringing act is reasonably related to the regulatory approval process. If they are not, as in the dual use situation in which an act both generates regulatory information but is also used for marketing, the act is not "solely for uses reasonably related" to regulatory approval.

Petitioner and the United States short circuit the analysis by asking whether an "experiment," for example, could generate regulatory information. Such a test focuses only on the objective half of the inquiry and improperly suggests that "reasonably related" should modify "act of infringement" instead of the *purpose* of the infringing act.

However, it is necessary, but not sufficient, that a particular class of infringing acts, such as pre-clinical experiments, can be put to regulatory uses. The presence of "solely" in the statute demonstrates that Congress did not intend to immunize all acts that might reasonably be related to FDA approval. Only those acts that are solely used for regulatory approvals are exempt.[4]

Once "act" and "use" are properly distinguished from each other in the context of Section 271(e)(1), it also becomes clear that the "solely for uses" requirement addresses the problem of hindsight in applying the exemption. Indeed, the temptation, to which others fall prey, is to view the drug discovery process teleologically by looking back from the perspective of successful drug screens and consummated IND applications. Such a focus is understandable – the select therapeutics that make it through are the valuable ones. However, by focusing only on the successes (and near misses) the reality of the research process is warped. Every assay and experiment appears directed toward (and reasonably related to) the FDA approval process. The presence of the subjective requirement that acts of infringement must be "solely for" the regulatory approval process returns the focus to the purpose of an "act" at its inception by evaluating what the act is "for" before its fate appears preordained.

In reality, the drug development process is highly uncertain. Some estimate that as many as one thousand different medicines must be tested in order to yield one that enters clinical trials. *See* Tufts Center for the Study of Drug

---

[4] Likewise, even though an act of infringement might reasonably be used for a non-regulatory purpose, such as marketing, the act will still be exempted if used solely for regulatory purposes.

Development, *Backgrounder: How New Drugs Move Through The Development and Approval Process* (November 1, 2001) *at* http://csdd.tufts.edu/NewsEvents/RecentNews.asp?newsid=4. The pre-IND sieve that screens drug candi-dates is basic research. Until an IND is filed for a particular therapeutic, a significant if not predominant "use" of the acts of infringement is research and optimization apart from the generation of information that is required or desired by the FDA. When the research landscape is viewed from the perspective of the actor before an IND has been filed, it is clear that acts of infringement cannot be "solely for" the FDA approval process.

IV.

RESPECTING THE WORDS OF SECTION 271(e)(1) RIGHT-SIZES THE EXEMPTION AND ALIGNS IT WITH ITS ORIGINAL PURPOSE

As demonstrated above, for otherwise infringing activity to qualify for the Section 271(e)(1) exemption, it must be used "solely" for purposes of developing and submitting information for regulatory approvals. As Judge Schwarzer explained in *Scripps*, the legislative history confirms that this interpretation of the statute aligns with the purpose behind the exemption. *Scripps* at 1396 ("This interpretation accords with the intent of Congress in enacting § 271(e)(1).").

When the rhetoric is stripped away, there is not serious dispute about the central purpose behind the enactment of Section 271(e)(1). As documented below, the statute was a carefully circumscribed exemption. It authorized only *de minimis* uncompensated patent infringement *solely* for the regulatory approval process. It was

intended to permit generic drug makers to perform FDA required bioequivalency testing, which necessarily involves the infringement of the proprietary drug maker's patent rights. The purpose of such testing is to allow the generic drug maker to prove that the proposed generic drug is effectively the same as the proprietary drug before the patents on the proprietary drug expire. This enables the fulfillment of the ultimate goal of having approved generic drugs ready for the market promptly upon the expiration of the patents covering the proprietary drug so there is no *de facto* patent extension. Because the generic drug makers are not defining a new drug, and a market for the drug has already been established, the exemption is needed for the basic bioequivalency testing. Of course, the purpose of this limited testing is for FDA approval.[5]

Petitioner concedes that Congress' intent in enacting Section 271(e)(1) was to authorize only "*de minimis*" and "insubstantial" uncompensated infringement. Petitioner's Brief at 36 ("the nature of the interference with the rights of the patent holder would not be substantial, but *de minimis*") (quoting H.R. Rep. No. 857, at 8, *reprinted in* 1984 U.S.C.A.N.N. 2684, 2692) (emphasis and citations omitted); and at 37 ("infringement is *de minimis* just as Congress intended").

The Federal Circuit explained that a central purpose of Section 271(e)(1) was to "ensure that a patentee's rights

---

[5] Although FDA-required experimentation, like any experimentation, might have some ancillary value for product development, under Section 271(e) such value cannot be more than incidental. If it were more than incidental, it would constitute a purpose for the infringement that would render the infringement not "solely" for use in the regulatory process.

did not *de facto* extend past the expiration of the patent term because a generic competitor also could not enter the market without regulatory approval." *Integra Life Sciences 1, Ltd. v. Merck KG*, 331 F.2d 860, 865 (Fed. Cir. 2003). Petitioner does not contest this analysis of the legislative history. Likewise, Petitioner does not meaningfully deny that the legislative history reflects that Congress foresaw only "a limited amount of testing so that generic manufacturers can establish the bioequivalency of a generic substitute." H.R. Rep. No. 857, at 8, *reprinted in* 1984 U.S.C.A.N.N. 2684, 2692.

On the other hand, Petitioner and its allies do not cite any legislative history that suggests the purpose of the legislation was to exempt broadly drug development from the patent laws.

Where Amici and Petitioner really part company is on the *legal* consequence of the legislative history. Petitioner reasons that, because the above-quoted legislative history did not trump the statutory language and structure in *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661 (1990), it should not do so here. Indeed, Petitioner's central argument is that the legislative history cannot narrow a broad statute. Petitioner's Brief at 35 (the legislative history "cannot overcome unambiguous statutory language").

The statutory interpretation issue here is far different than that presented in *Lilly*, and Petitioner and its allies uniformly ignore that important difference. Here, the narrow scope of the exemption suggested by the legislative history is *mandated* by the statutory language "solely for uses," as demonstrated above. It is not in *conflict* with the statute's structure as it was found to be in *Lilly*.

In sum, here, both the statutory language and the legislative history support the conclusion that the Section 271(e)(1) exemption is confined to infringing acts "solely" used for the regulatory approvals such as bioequivalency testing. If activities other than bioequivalency testing for generic substitutes fall within some of the broader language of the statute, they must be protected pursuant to standard statutory interpretation principles. However, by its plain terms, activities not used *solely* for regulatory approvals fall outside the exemption because the statute says so. The legislative history reinforces, rather than undermines, this conclusion.

V.

THE EXEMPTION SOUGHT BY PETITIONER WILL SET BACK, NOT ADVANCE, PUBLIC HEALTH

The broad infringement exemption sought by Petitioner and its allies will harm public health in the long run, not help it. The far-reaching exemption they seek essentially suspends the patent laws as it relates to the drug research and development process. Indeed, Petitioner goes so far as to suggest that if drug research and development relates to the "safety, efficacy, mechanism of action, pharmacology, or pharmacokinetics" any infringement is cost-free because the FDA is interested in those broad topics. *See* Petitioner's Brief at 276, United States' Brief at 25-26. One of the more candid drug company briefs expressly pleads that "the FDA exemption should be generously interpreted" because to do otherwise would "complicate" the drug development process. Brief of the Amicus Curiae Genentech, Inc. and Biogen Idec., Inc. at 6-7.

While there may be some superficial appeal to the emotional argument that patent rights complicate product development and increase prices, the Constitution and experience teach otherwise. While those with a short-term view see the cost of patent enforcement, those with a longer perspective appreciate the incentives created by patent rights in this field, at least as much as in other fields.

These truths are especially relevant in the area of drug discovery tools. Modern drug discovery is buoyed by the rising and swelling tide of innovation in the area of research tools. Some tools make the discovery of new drugs and therapies possible. Examples of such tools are technologies that replicate DNA, decode genes, screen candidate drugs, validate targets and provide manufacturing and analytical standards and tests. Other tools enhance the performance of candidate therapeutics or diagnostic products. Examples of these tools include medicinal chemistries and formulations that make whole classes of drugs work better.

Tools are the common denominator across all possible therapeutic agents – tools are necessary to isolate, analyze, qualify, and optimize every potential drug, and are employed at every stage of the development process. In some cases, a tool is employed to work a permanent improvement to a class of therapeutics. Concerns about preserving the value of tool patents in the face of free-riding by pharmaceutical companies during the term of development are no less implicated where the "tool" is an optimization that is incorporated into a final product that is sold, potentially, years after patents on the tool have expired.

If new drugs are the "fish," the research tools are the fishing poles. If the patent-free development of this year's drugs is perceived by some as in their short-term interest, the patent-incentivized development of future research tools is in the interest of our descendants for generations to come.

One group of commentators explained in stark terms the risk to tool patents posed by an overbroad reading of Section 271(e)(1):

> Since there is generally no use for research tools other than in the research and development process and a third party's interest is to use the technology rather than resell it, extension of the § 271(e)(1) exemption far upstream in the research-and-development process renders research tool patents essentially unenforceable. Consequently, such staple technologies of biotechnology industry patents as recombinant cells, transgenic animals, or high-throughput screening methods and their uses will be essentially unprotectable, thus erasing the value of much of the biotechnology industry and undercutting incentive for further research in this essential area. Because a biotech company would have no proprietary rights to any FDA-approved commercial product discovered or developed by a third party using its patented research tool, the value of these companies is severely and perhaps fatally undercut.

Kevin E. Noonan, *Paradise Lost: The Uncertain Future Of Research Tool Patents*, 15 No.3 J. Proprietary Rts. 1, 8.

Petitioner does not deny that research tools are vitally important or even that patent protection is important for such tools. Instead, it focuses its energy attempting to

persuade this Court that "research tools" are not (strictly speaking) at issue in this case. Petitioner's Brief at 41 ("it bears emphasis that this case does not present the research tool question."). Petitioner's fallback position is that even if the *rules* created by this case impact tool patents, the Court should not let that get in the way of creating the broad exemption they seek. *Id.* ("the possibility of a marginal encroachment on research tool patents has little bearing on whether Congress, in 1984, intended to insulate preclinical experiments from patent infringement claims."); *see also* United States' Brief at 28 (containing an entire section entitled "The Uncertain Status of Patents for Research Tools Under The Exemption Provides No Basis For Artificially Narrowing The Exemption As Applied To Other Patents").

In fact, an overbroad interpretation of Section 271(e)(1) unquestionably creates grave risk for the biotech industry generally and tool patents specifically. Even the champions of a broad exemption raise the possibility of restrictions that this Court could invoke to protect tool patents. For example, Petitioner explains that, under certain circumstances, "a court might conclude that the use of a patented research tool is not 'reasonably related' to the development of information for the FDA." Petitioner's Brief at 43. Petitioner also notes that the "patented invention" covered by Section 271(e) may not be interpreted to include tool patent inventions. *Id.* Likewise, the United States observes that "Congress may not have intended to include research tools within the scope of the affected inventions." United States' Brief at 29.

Others explain persuasively why these protections should in fact be invoked by this Court to minimize any damage to the biotech community and tool makers; Amici

will not belabor those points. In any event, giving "solely" its undeniable meaning goes a long way towards ensuring that the balance struck by Congress is honored and that the exemption does not threaten innovation broadly. As explained above, respecting the word "solely" is also mandated by the straightforward application of standard statutory interpretation principles. Acknowledging the entirety of the text of the statute is not only common sense, but it points to the right result.

IV.

CONCLUSION

For the reasons addressed above, the judgment of the court of appeals should be affirmed.

Respectfully submitted,

Amici Curiae
Applera Corporation
Isis Pharmaceuticals, Inc.

EDWARD R. REINES
Counsel of Record

PAUL T. EHRLICH
WEIL, GOTSHAL & MANGES LLP
201 Redwood Shores Parkway
Fifth Floor
Redwood Shores, CA 94065
(650) 802-3000

APPENDIX

"solely"

Merck	Certainly, there is no categorical limitation implicit in the exemption's emphasis that infringement is excused "solely for [the] uses" described, and not for other "uses." Contrary to the Court of Appeals' insinuation, see P.A. 10a, that adverb offers no assistance in discerning which phases of drug development are covered by the FDA exemption. It means only that a drug innovator's freedom to use a patented invention under the FDA exemption is not a license to infringe in other ways, such as commercial exploitation. *See, e.g., Intermedics, Inc. v. Ventritex, Inc.*, 775 F. Supp. 1269, 1275 (N.D. Cal. 1991), *aff'd*, 991 F.2d 808 (Fed. Cir. 1993). (brief p.29)
EON Labs	When words of elasticity are used, this Court "construe[s] language in its context and in light of the terms surrounding it." *Leocal v. United States*, 125 S.Ct. 377, 382 (2004) (interpreting the elastic word "use" in relation to deportation of immigrant for drunk driving). It is also true that the plain text uses the term "solely" that imbues a limitation to the statute. It is also true that statutes must be construed to give fidelity to each term in the statute as opposed to interpreting it to render any one particular term meaningless. The Federal Circuit violated these rules by focusing on the term "solely" as opposed to interpreting this term in conjunction with the term "reasonably" for when one does so, the statutory construction results in a more liberal interpretation than what the Federal Circuit gave. If Congress had intended that the scope be so narrow, then why did Congress insert the term "reasonably" into the statute? *Integra*, 331 F.3d at 866-67. (brief p.6)

US Gov't	The court of appeals noted (Pet. App. 11a) that "[t]he term 'solely' places a constraint on the inquiry into the limits of the exemption." That constraint, however, is not relevant to the interpretive question here. The statute authorizes making, using, selling, or offering to sell a patented invention "solely for uses reasonably related to the development and submission of information" to FDA. 35 U.S.C. 271(e)(1). Because "solely" modifies "uses," it makes clear that a researcher is not protected by the exemption insofar as he or she engages in uses that are not, in their entirety, reasonably related to the development and submission of information to FDA. "Solely" does not, however, modify "reasonably related." Thus, as long as the full extent of a particular use is reasonably related to the development and submission of information, that use is protected even if it also advances other objectives, such as product development or marketing. *See Amgen, Inc. v. Hoechst Marion Roussel, Inc.*, 3 F. Supp. 2d 104, 107-108 (D. Mass. 1998). But the exemption is inapplicable to the extent that a portion of the particular use at issue does not satisfy the reasonable relationship test. (brief p.20)

BIO	Section 271(e)(1)'s safe harbor is thus tied also to "veterinary biological products" and, more critically, it exempts infringement of "a patented invention" when that infringement was done "solely for uses reasonably related to the development and submission of information" under a Section 271(e)(1) Federal law. *Id.* Similarly, "solely" in Section 271(e)(1) was not intended by Congress to modify "a patented invention." If that were the case, the only patented inventions falling within Section 271(e)(1)'s safe harbor are patented inventions that have few other uses except those "reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs or veterinary biological products." *Id.* Even pioneering drugs would not fall within the ambit of such a limited description. (brief p.6)
Sepracor	The Federal Circuit thus rejected the view that the word "solely" in § 271(e)(1) "requires that the original exemption of the making, using and selling activities be revoked when the resulting data is later used for non-FDA reporting purposes." *Id.* at 1524. (brief p.8-9)

AARP	The statutory language that using a patented invention "solely for uses reasonably related to the development and submission of information" under a federal law regulating drugs is both plain and broad. The Federal Circuit determined that the use of the words "solely" and "reasonably related" meant there was some limitation to the scope of the exemption, a logical reading of these words of limitation. But in its attempt to define the outer boundaries of the exemption, it failed to appreciate the breadth of the heart of the exemption. (brief p.4)